Department of Veterans Affairs **VHA DIRECTIVE 2001-004**
Veterans Health Administration
Washington, D.C., 20420 **January 22, 2001**

FUNDING OF LEFT VENTRICULAR ASSIST DEVICES (LVADs)

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines the policy regarding the funding of left ventricular assist devices (LVADs).

2. BACKGROUND

a. During the past decade, LVADs as a mechanical bridge to transplantation have progressed from the experimental arena to accepted therapy. Approved by the Food and Drug Administration (FDA) for this purpose, LVADs are now utilized as a standard of care for those critically ill patients who are waiting to undergo heart transplantation. An LVAD may be appropriate for patients whose condition deteriorates while waiting for an appropriate donor, and who cannot be supported by less invasive interventions. The Department of Veterans Affairs (VA) has utilized LVAD support for veterans since it became available and will continue to do so.

b. Intense investigation is underway by many non-VA institutions to use the LVAD as a bridge to recovery or as definitive therapy for heart failure (HF) patients. As definitive therapy, an assist device would be used for a specific subset of heart failure patients over the long term because based on specific criteria such as age or absolute contraindications, they are not and cannot be considered for transplantation. If and when this use is approved by the FDA, VA will issue new guidance.

c. Heart failure is a growing problem worldwide and medical (pharmacological) therapies have yet to supplant heart transplant as the definitive therapy. However, there are far more people waiting for heart transplant than can be accommodated by the number of donors (averages about 2,400 hearts per year). Of the approximately 4,000 registrants on the heart transplant waiting list, only about 2,300 patients receive heart transplants each year. These numbers have not changed significantly since 1989. Meanwhile, both pharmacological and mechanical device therapies have been utilized to sustain gravely ill patients with heart failure.

d. VA is a provider of heart transplants. This service is provided in-house at the Richmond VA Medical Center (256 transplants since 1980) and the Salt Lake City VA Medical Center (201 transplants since 1985). VA purchases this service via sharing agreements at several other facilities, including: Madison, WI; Nashville, TN; Palo Alto, CA; the University of California at San Diego and, in very small numbers, elsewhere.

3. POLICY: It is VHA policy that VA will not accept fiscal responsibility for LVADs placed outside the VA transplant system. LVADs are classified as a Prosthetics Surgical Implant, are funded as a prosthetic item through centralized prosthetic funding, and are purchased via the Prosthetic Software Package in Veterans Health Information Systems and Technology Architecture (VistA).

THIS VHA DIRECTIVE EXPIRES JANUARY 31, 2006

4. ACTION

a. Each facility Director, or designee, has the responsibility for funding LVADS for their respective patients approved for the VA transplant program. The proper Budget Object Code (BOC) for obligating LVAD funds is BOC 2692, Cost Center 8202.

b. Eligible veterans on temporary mechanical assist devices at a non-VA facility may be referred to VA for consideration of heart transplantation. If the referral to VA is approved, the patient will be transferred to a VA transplant center. VHA Headquarters is responsible for only the transplant episode costs.

c. VHA Headquarters Prosthetic and Sensory Aids Service Strategic Healthcare Group is responsible for tracking the use of these devices throughout VA. ***NOTE:*** *This item is discussed with the VA Heart Transplant Board at each of its annual meetings.*

5. REFERENCES: None.

6: FOLLOW-UP RESPONSIBILITY: The Chief Consultant, Acute Care Strategic Healthcare Group (111) is responsible for the contents of this Directive. Questions may be referred to the VA Transplant Program at 1-800-60-HEART or faxed to (202) 273-9141.

7. RESCISSIONS: None. This VHA Directive will expire January 31, 2006.

Thomas L. Garthwaite, M.D.
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 1/24/2001
FLD: VISN, MA, DO, OC, OCRO, and 200 - FAX 1/24/2001